



Attorney Docket: JWB-2001-1-P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Harold Mermelstein et al.
Serial No. : 10/037,526
Filed : January 4, 2002
For : Composition and Method for
Treatment of Vaginal Dryness
Art Unit : 1615
Examiner : Rachel M. Bennett

DECLARATION OF FRANK MARCHESE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

I, FRANK MARCHESE, declare the following under the penalty of perjury:

1. I am a co-inventor of the invention described and claimed in the above-referenced patent application.

2. I obtained a B.S. degree in Organic Chemistry in 1957 from Iona College, New Rochelle, New York and M.S. degree in Organic and Physical Chemistry in 1960 from St. John University, Uniondale, New York.

3. I have been informed, and I am therefore aware, that U.S. Patent No. 6,242,012 B1 issued June 5, 2001 to Newmark et al., and Patent Publication No. 2003/0045829 A1 (Gehling et al.) published March 6, 2003 have been cited against the claims of the above-referenced patent application.

4. Gehling et al. publication is based on a patent application which, on its face, has a filing date of December 21, 2001, and is based on Provisional Application No. 60/315,882 filed in the United States Patent and Trademark Office on August 29, 2001.

5. Prior to August 29, 2001 I, together with my co-inventor Harold Mermelstein, conceived and reduced to practice in this country, the invention which is claimed in the above-referenced patent application. The annexed pages are copies of pages from my notebook in which I described the experiments relating to the preparation of the various compositions.

6. Prior to August 29, 2001 I prepared the compositions set forth in my Laboratory Notebook pages which bear the designation EXP 7, Experiment 11 and Experiment 15, copies of which are annexed hereto as Exhibits A, B and C, respectively. Also annexed hereto is Exhibit D, which is a copy of Experiment 10 which is referred to in Experiment 11.

7. Also prior to August 29, 2001, the compositions prepared in Experiments 7, 11 and 15 were submitted to my co-inventor, Harold Mermelstein, for evaluation as vaginal moisturizers.

8. Upon information and belief, prior to August 29, 2001, and said Harold Mermelstein evaluated said compositions as vaginal moisturizers and reported the results to me orally and in writing. In addition, he also compared the effectiveness of said compositions to the composition disclosed in Newmark et al. and found that the compositions described in annexed Exhibits A, B and C to be superior to the composition disclosed by Newmark.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued therein.

Dated: 8/04/2004

Frank Marchese
Frank Marchese



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DECLARATION OF HAROLD MERMELSTEIN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

I, HAROLD MERMELSTEIN, declare the following under the penalty of perjury:

1. I am a co-inventor of the invention described and claimed in the above-referenced patent application.

2. I am a Board Certified Medical Doctor specializing in Dermatology. I received my medical degree from New York Medical College in 1975.

3. I have been informed, and I am therefore aware, that U.S. Patent No. 6,242,012 B1 issued June 5, 2001 to Newmark et al., and Patent Publication No. 2003/0045829 A1 (Gehling et al.) published March 6, 2003 have been cited against the claims of the above-referenced patent application.

4. I have read the Declaration of my co-inventor Frank Marchese which is being filed concurrently herewith and I have tested in this country, for vaginal dryness, the formulations described in Exhibits A, B and C of the Marchese Declaration and I have compared these formulations with the Newmark et al. formulation. All tests were performed and the results completed prior to August 29, 2001.

5. The formulation of the Newmark et al. patent which was tested is set forth below (all percents are weight basis):

Distilled Water – Sterilized	93.15
SCMC	5
Dong Quai	.08
Black Cohosh	.04
Chasteberry	.04
Evening Primrose	.17
Olive Oil	1.5
Germal II	<u>.02</u>
TOTAL	100.00

6. Twelve patients were recruited to attempt a comparison between the Newmark et al. formulation and the formulations set forth in said Exhibits A, B and C. All patients were instructed to apply the same amount of each formula and to report the results. Two out of the twelve patients did not use the Newmark et al. formula after two days because they felt the product was irritating. One patient did not follow up. Nine patients used the Newmark et al. formula for one to two times daily for two weeks. Eight out of the nine patients reported no change or improvement in vaginal moisture but only one patient noted slight improvement. Ten out of the twelve patients who used the formulations described in said Exhibits A, B and C noted improved moisturization. One patient did not follow up and one patient did not report any improvement. Out of the ten patients who noted improved moisturization, five reported remarkably reduced discomfort during intercourse. One patient who was using these formulations was coincidentally examined by a gynecologist and was told by her gynecologist that her vaginal area looked healthier.

7) The aforementioned clinical data clearly establish that the formulations described in accordance with the invention of our patent application is markedly superior to the Newmark et al. formulation and, on the basis of my experience, I attribute this superiority to differences in the combination of ingredients used to prepare our formulas as compared to the formulation disclosed by the Newmark et al patent.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued therein.

Dated: 8/4/04

Harold Mermelstein
Harold Mermelstein